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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,377	03/28/2005	Hyun-Ah Kang	P26459	7630
7055	7590	11/06/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.			MOORE, WILLIAM W	
1950 ROLAND CLARKE PLACE			ART UNIT	PAPER NUMBER
RESTON, VA 20191			1656	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/518,377	KANG ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	William W. Moore	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 20 January 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 1-17 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

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## DETAILED ACTION

*Restriction*

Restriction is required under 35 U.S.C. §§ 121 and 372.

Pursuant to Applicant's Preliminary Amendment to the claims filed 28 December 2004, this application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1. Claims 1-4, drawn to a polynucleotide encoding the *Hansenula polymorpha* protease yapsin1 having the amino acid sequence set forth in SEQ ID NO:2, and to the encoded protease yapsin1.

Group 2. Claim 5, drawn, if properly stated, to amino-terminal fragment of the amino acid sequence set forth in SEQ ID NO:2 that serves as a secretion signal peptide.

Group 3. Claims 6-17, drawn to at least three species of *Hansenula polymorpha* strains modified by deletion or disruption of a chromosomal polynucleotide region encoding the *Hansenula polymorpha* protease yapsin1 and to methods of use of each of the species in the recombinant expression of a transforming polynucleotide encoding a heterologous polypeptide.

The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group 1 has the special technical feature of the structure, which is its coding capacity, of the claimed polynucleotide for an integral, catalytically-active protease yapsin1, as well as the structure of the encoded, integral, catalytically-active protease yapsin1 having the amino acid sequence set forth in SEQ ID NO:2, while the special technical feature of the invention of Group 2 is the unspecified structure of a fragmentary peptide capable of mediating the transmembrane transport of a protein in the yeast *Hansenula polymorpha*, thus the inventions of Groups 1 and 2 share no same or corresponding special technical feature.

The inventions listed as Groups 1 and 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

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corresponding special technical features for the following reasons: The invention of Group 1 has the special technical feature of the structure, which is its coding capacity, of the claimed polynucleotide for an integral, catalytically-active protease yapsin1, as well as the structure of the encoded, integral, catalytically-active protease yapsin1 having the amino acid sequence set forth in SEQ ID NO:2, while the special technical feature of the invention of Group 3 is the lack of a polynucleotide capable of encoding an integral, catalytically-active protease yapsin1, thus the inventions of Groups 1 and 3 share no same or corresponding special technical feature.

The inventions listed as Groups 2 and 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group 2 has the special technical feature of an unspecified structure of a fragmentary peptide capable of mediating the transmembrane transport of a protein in the yeast *Hansenula polymorpha*, while the special technical feature of the invention of Group 3 is the lack of a polynucleotide capable of encoding an integral, catalytically-active protease yapsin1, thus the inventions of Groups 2 and 3 share no same or corresponding special technical feature.

This application contains claims 6-17 directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. The *H. polymorpha* *hpyps1Δ-pMOXhPTH* strain of Accession No. KCTC 10282BP.
- B. The *H. polymorpha* *hpyps1Δ-YHSA12* strain of Accession No. KCTC 10283BP.
- C. The *H. polymorpha* *hpyps1Δ-pYHSA13-TIMP2* strain of Accession No. KCTC 10284BP.

The claims 6-17 are deemed to correspond to the species listed above in the following manner:

Species A comprises claims 6-9, 12, 13 and 15, and claim 14 in part.

Species B comprises claims 6-8, 10, 12, 13 and 16, and claim 14 in part.

Species C comprises claims 6-8, 11-13 and 17, and claim 14 in part.

The following claim(s) are generic: Claims 6-8, 12 and 13.

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The species A and B listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of the invention of species A is the capacity of a transforming polynucleotide to encode human parathyroid hormone, while the special technical feature of the invention of species B is the capacity of a transforming polynucleotide to encode human serum albumin, thus the inventions of species A and B share no same or corresponding special technical feature.

The species A and C listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of the invention of species A is the capacity of a transforming polynucleotide to encode human parathyroid hormone, while the special technical feature of the invention of species C is the capacity of a transforming polynucleotide to encode a chimeric polypeptide comprising a human tissue inhibitor of metalloproteinase-2, thus the inventions of species A and C share no same or corresponding special technical feature.

The species B and C listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of the invention of species B is the capacity of a transforming polynucleotide to encode human serum albumin, while the special technical feature of the invention of species C is the capacity of a transforming polynucleotide to encode a chimeric polypeptide comprising a human tissue inhibitor of metalloproteinase-2, thus the inventions of species B and C share no same or corresponding special technical feature.

A telephone call was made to Mr. Stephen M. Roylance on 3 November 2006 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even

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though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

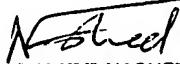
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
3 November 2006

  
NASHAAT T. NASHED PH.D.  
PRIMARY EXAMINER